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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

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Douglas J. Taylor, Esq.  
General Mills, Inc.  
P.O. Box 1113  
Minneapolis, MN 55440

EXAMINER
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GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/782,320

Applicant(s)

VAN LINGERICH, BERNHARD H.

Examiner

Michel Graffeo

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.

4a) Of the above claim(s) 26, 32-33, 41, 43, 47, 50, 60, 68, 71, 86-89, 94, 98-100 and 106-107 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9 mar 06</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 .

Continuation of Disposition of Claims: Claims rejected are 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 .

## **DETAILED ACTION**

### ***Status of Action***

Claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 are examined.

Applicant has canceled claim 63 and provided arguments for the patentability of claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 in the response filed 9 March 2006. The claim set provided by Applicant includes claims 76 and 90 as pending. These claims have been withdrawn in the previous Office Action, mailed 13 December 2005, as not being drawn to the elected species.

Applicant's arguments, see response, filed 9 March 2006, have been fully considered and are persuasive to the extent that the rejection under 35 USC §112 is withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Maintained Claim Rejections - 35 USC § 103***

Claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,187,321 to Mutai et al.

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Mutai et al. teach a tablet or powder formulation (in current claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 3 line 4) comprising a probiotic (Bifidobacterium and Lactobacillus species), starch (in current claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 5 Example 3) and fat (25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 2 lines 35-43) wherein the fat and probiotic can be combined and dried and further mixed with starch and further wherein the resulting product can be used in a food product (see col 2 lines 11-15).

Although Mutai et al. do not specifically recite the resultant amounts of probiotic and starch in the final product, Mutai et al. do approximate same (20 fold amount of starch leaves 5% for the dried milk/probiotic component) and one of ordinary skill in the art would have routinely optimized the amounts of each component based on the ultimate end use of the product and in light of the teachings in Mutai et al. in col 2 lines 35-40 which read that no "restriction is imposed on the composition of the media used for the mixed cultivation of obligatory anaerobic strains..." and further where Mutai et al. recite that no "restriction is placed on the means to process the culture or the type of final products as long as they do not kill the Bifidobacterium." (see col 3 lines 4-6).

Again Mutai et al. do not specifically recite the tablet dimensions, specific density of the product or release rates of the products. Nonetheless, since the products as claimed are the same as those in the art, the functional characteristics thereof must be the same. A product cannot, absent evidence to the contrary, be separated from its

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characteristics particularly when it is used for the same purpose as that in the art.

Dimensions of the tablet, on the other hand, are not material to patentability in that they are routinely optimized by one of ordinary skill in the art and the tableting industry as a whole depending on target market for example. Again, Mutai et al. speaks to tablet size wherein it is recited that no "restriction is placed on the means to process the culture or the type of final products as long as they do not kill the Bifidobacterium." (see col 3 lines 4-6). Thus, the reference teaches and makes prima facie obvious how to use the claimed invention at the time that it was made.

***Response to Arguments - 35 USC § 112***

Applicant's arguments filed 9 March 2006 have been fully considered and are persuasive for the reasons of record.

***Response to Arguments - 35 USC § 103***

Applicant's arguments filed 9 March 2006 have been fully considered but they are not persuasive. Applicant argues that Mutai et al. does not teach that "dried starch" is a plasticized material. Nonetheless, since the products as claimed are the same as those in the art, the functional characteristics thereof must be the same. A product cannot, absent evidence to the contrary, be separated from its characteristics particularly when it is used for the same purpose as that in the art.

Applicant further argues that the matrix claimed in claims 42, 52, 69 and 83-84 is not taught in Mutai et al. Although durum wheat was not taught in Mutai et al., starch is

taught in the Specification as a matrix material (see page 8 lines 25-30). Absent a teaching of the elected species, the Examiner may choose the next species for examination. To that end, the Examiner has chosen starch (as taught in Mutai et al. Example 3 col 5).

The claims are directed to a product and to that end the Examiner does not need to find motivation for using any particular amount of actives or in this case, the milk. To that end the rejection is proper with respect to the inclusion of milk/probiotic in the Mutai et al. reference. Similarly, the Examiner is not required to point to any recognition or appreciation in the reference for the claim limitation, in this case the fat from the milk as a release-rate controlling component (see claim 31).

Finally, claim 21 has been canceled and to that extent any arguments for the patentability thereof is moot. With respect to the limitation that the encapsulant and matrix material are substantially homogeneous, see col 5 Example 1 which teaches the homogenization of the milk/bacterial culture.

As noted in the prior office action, Neither the IDS filed on or about 26 March 2001 nor the IDS filed on or about 8 March 2002 have a PTO-1449 attached. No IDS is present in the file having a filing date on or about 21 December 2001.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5 June 2006  
MG

 6/11/06  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**